

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q95047

Yukako FUKUHIRA, et al.

Appln. No.: 10/580,029

Group Art Unit: 1633

Confirmation No.: 7517

Examiner: Fereydoun Ghotb Sajjadi

Filed: May 19, 2006

For: TISSUE REGENERATION SUBSTRATE, COMPLEX THEREOF WITH CELLS, AND
METHOD FOR ITS PRODUCTION

**INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. §§ 1.97 and 1.98**

MAIL STOP AMENDMENT

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure under 37 C.F.R. § 1.56, Applicant hereby notifies the U.S. Patent and Trademark Office of the documents which are listed on the attached PTO/SB/08 (modified) form and/or listed herein and which the Examiner may deem material to patentability of the claims of the above-identified application.

One copy of each of the listed documents is submitted herewith, except for the following: U.S. patents and/or U.S. patent publications; and co-pending non-provisional U.S. applications filed after June 30, 2003. Also submitted herewith is a Japanese Office Action dated February 9, 2010 for JPA No. 2005-515700, which is a counterpart to the present application. Documents 1-3 in the Japanese Office Action were submitted in an IDS on December 31, 2007, and documents 4-5 were submitted in an IDS on December 13, 2006, and therefore Documents 1-5 will not be submitted again.

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The present Information Disclosure Statement is being filed after the later of three months from the application's filing date and the mailing date of the first Office Action on the merits, but before a Final Office Action, Notice of Allowance, or an action that otherwise closes prosecution in the application (whichever is earlier), and therefore Applicant is filing concurrently herewith a Statement Under 37 C.F.R. § 1.97(e). No fee under 37 C.F.R. § 1.17(p) is required.

In compliance with the concise explanation requirement under 37 C.F.R. § 1.98(a)(3) for foreign language documents, Applicant submits the following concise explanation of the relevance of each non-English reference indicated in the Japanese Office Action:

JPA2002-345455 (D2) describes a bioabsorbable porous scaffold for culturing cartilage cells made of glucosaminoglycan and phospholipid. It also suggests that the scaffold may have honeycomb structure as a preferred embodiment.

However, it only describes a scaffold, wherein glucosaminoglycan bears phospholipid by covalent bond. It is silent about how to prepare honeycomb structure as small as the present invention. In addition, the present invention does not use glucosaminoglycan.

JPA07-135961 (D3) describes a scaffold for vascular endothelial cells made of cell-adhesive protein and phospholipid.

However, the present invention does not use cell-adhesive protein.

Both JPA2002-335949 (D4) and JPA2001-157574 (D5) describe a biodegradable film having honeycomb structure of similar hole size to that of the present invention, D4 also suggests that the honeycomb film can be used for cell culture.

However, the honeycomb structure of D4 and D5 was prepared by using amphiphilic polymer prepared by covalently bonding hydrophilic moieties to hydrophobic polymer such as polylactic acid.

The present invention does not use amphiphilic polymer. Instead, a mixture of hydrophobic polymer such as polylactic acid and phospholipid that is not covalently bonded to the polymer is used.

Nishikawa (D6) describes a preparation method for honeycomb film made of polylactic acid or polycaprolactone having similar hole size to that of the present invention. However, according to D6, amphiphilic polymer must be added to polylactic acid or polycaprolactone for preparing honeycomb structure.

The present invention never uses amphiphilic polymer, but rather a low molecular weight compound such as phosphatidylethanolamine is used.

Nishikawa (D7) describes a honeycomb film made of amphiphilic polymer such as Lac or Cap. See figure 3. D7 also shows the film can be used for culturing hepatocytes.

Again, according to D7, amphiphilic polymer is necessary for preparing honeycomb structure. In contrast, the present invention achieved the preparation of a honeycomb film from a hydrophobic polymer such as polylactic acid by not mixing amphiphilic polymer such as Cap.

The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicant does not waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

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The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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23373

CUSTOMER NUMBER

Date: May 7, 2010